

IN RE APPLICATION OF:
M. A. CAWTHORNE et al.

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FILED: **MARCH 20, 2000**

FOR: **METHOD AND COMPOSITIONS FOR
TREATING HYPERLIPIDEMIA AND
OTHER CONDITIONS**

EXAMINER: **A. Mohammed**
ART UNIT: **1653**

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Date of Deposit: June 17, 2002

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CLEAN VERSION OF PENDING CLAIMS

Sub C31
1. (Amended) A method of treating hyperlipidemia in a patient in need of such treatment, said method comprising administering a therapeutically effective amount of a somatostatin type-5 receptor agonist to said patient.

Claim 1
6. (Amended) A method of lowering the amount of triacylglycerols, glycerol or cholesterol in the blood of a patient in need of such lowering, said method comprising administering a therapeutically effective amount of a somatostatin type-5 receptor agonist to said patient.

8. A method of claim 6, wherein said method comprises lowering the amount of triacylglycerols in said patient.

18. A method of claim 6, wherein said method comprises lowering the amount of cholesterol in said patient.

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32. (New) A pharmaceutical composition for the treatment of hyperlipidemia in a patient in need thereof, comprising a therapeutically effective amount of a somatostatin type-5 receptor agonist, wherein said therapeutically effective amount

is an amount that is effective for the treatment of hyperlipidemia in said patient.

33. (New) A pharmaceutical composition according to claim 32, wherein said somatostatin type-5 receptor agonist is a somatostatin type-5 receptor selective agonist.

34. (New) A pharmaceutical composition according to claim 32, wherein said somatostatin type-5 receptor agonist has a Ki of less than 2 nM for the somatostatin type-5 receptor.

35. (New) A pharmaceutical composition according to claim 32, wherein said somatostatin type-5 receptor agonist has a Ki for the type-5 somatostatin receptor that is at least 10 times less than its Ki for the somatostatin type-2 receptor.

36. (New) A pharmaceutical composition according to claim 32, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH₂, where a disulfide bond exists between the free thiols of the two Cys residues, or
H-D-Phe-Phe-Phe-D-Trp-Lys-Thr-Phe-Thr-NH₂.

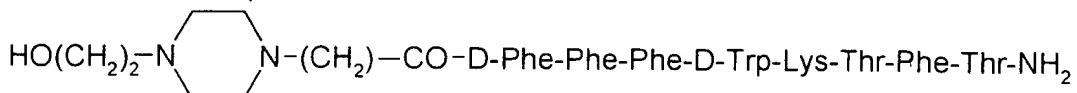
37. (New) A pharmaceutical composition according to claim 32, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Ser-Phe-Cys-NH₂;

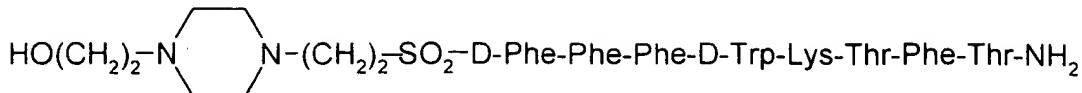
H-Cys-Phe-Tyr-D-Trp-Lys-Thr-Phe-Cys-NH₂;

H-Cys-Phe-Tyr(I)-D-Trp-Lys-Thr-Phe-Cys-NH₂;

wherein a disulfide bond exists between the free thiols of the two Cys residues in each of the foregoing agonists;



or



38. (New) A pharmaceutical composition for lowering the amount of triacylglycerols in the blood of a patient in need of such lowering, comprising a therapeutically effective amount of a somatostatin type-5 receptor agonist, wherein said therapeutically effective amount is an amount that is effective for lowering the amount of triacylglycerols in the blood of said patient.

39. (New) A pharmaceutical composition according to claim 38, wherein said somatostatin type-5 receptor agonist is a somatostatin type-5 receptor selective agonist.

40. (New) A pharmaceutical composition according to claim 38, wherein said somatostatin type-5 receptor agonist has a K_i of less than 2 nM for the somatostatin type-5 receptor.

41. (New) A pharmaceutical composition according to claim 38, wherein said somatostatin type-5 receptor agonist has a K_i for the type-5 somatostatin receptor that is at least 10 times less than its K_i for the somatostatin type-2 receptor.

42. (New) A pharmaceutical composition according to claim 38, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH₂, where a disulfide bond exists between the free thiols of the two Cys residues, or

H-D-Phe-Phe-Phe-D-Trp-Lys-Thr-Phe-Thr-NH₂

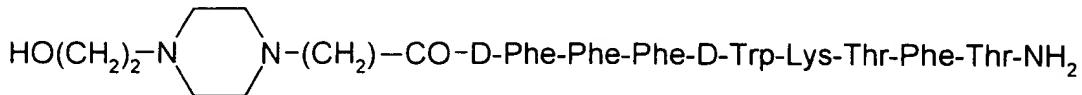
43. (New) A pharmaceutical composition according to claim 38, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Ser-Phe-Cys-NH₂:

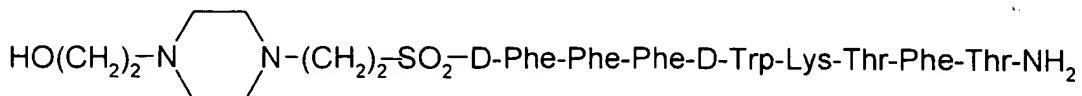
H-Cys-Phe-Tyr-D-Trp-Lys-Thr-Phe-Cys-NH₂:

H-Cys-Phe-Tyr(I)-D-Trp-Lys-Thr-Phe-Cys-NH₂:

wherein a disulfide bond exists between the free thiols of the two Cys residues in each of the foregoing agonists;



or



44. (New) A pharmaceutical composition for lowering the amount of glycerol in the blood of a patient in need of such lowering, comprising a therapeutically effective amount of a somatostatin type-5 receptor agonist, wherein said therapeutically effective amount is an amount that is effective for lowering the amount of glycerol in the blood of said patient.

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45. (New) A pharmaceutical composition according to claim 44, wherein said somatostatin type-5 receptor agonist is a somatostatin type-5 receptor selective agonist.

46. (New) A pharmaceutical composition according to claim 44, wherein said somatostatin type-5 receptor agonist has a Ki of less than 2 nM for the somatostatin type-5 receptor.

47. (New) A pharmaceutical composition according to claim 44, wherein said somatostatin type-5 receptor agonist has a Ki for the type-5 somatostatin receptor that is at least 10 times less than its Ki for the somatostatin type-2 receptor.

48. (New) A pharmaceutical composition according to claim 44, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH₂, where a disulfide bond exists between the free thiols of the two Cys residues, or
H-D-Phe-Phe-Phe-D-Trp-Lys-Thr-Phe-Thr-NH₂.

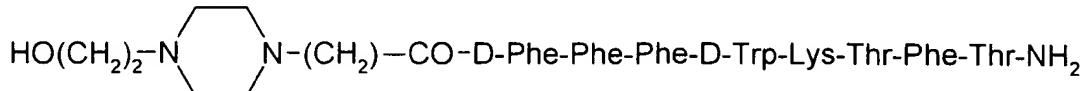
49. (New) A pharmaceutical composition according to claim 44, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Ser-Phe-Cys-NH₂;

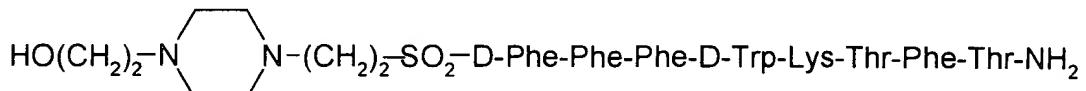
H-Cys-Phe-Tyr-D-Trp-Lys-Thr-Phe-Cys-NH₂;

H-Cys-Phe-Tyr(I)-D-Trp-Lys-Thr-Phe-Cys-NH₂;

wherein a disulfide bond exists between the free thiols of the two Cys residues in each of the foregoing agonists;



or



50. (New) A pharmaceutical composition for lowering the amount of cholesterol in the blood of a patient in need of such lowering, comprising a therapeutically effective amount of a somatostatin type-5 receptor agonist, wherein said therapeutically effective amount is an amount that is effective for lowering the amount of cholesterol in the blood of said patient.

51. (New) A pharmaceutical composition according to claim 50, wherein said somatostatin type-5 receptor agonist is a somatostatin type-5 receptor selective agonist.

52. (New) A pharmaceutical composition according to claim 50, wherein said somatostatin type-5 receptor agonist has a Ki of less than 2 nM for the somatostatin type-5 receptor.

53. (New) A pharmaceutical composition according to claim 50, wherein said somatostatin type-5 receptor agonist has a Ki

for the type-5 somatostatin receptor that is at least 10 times less than its K_i for the somatostatin type-2 receptor.

54. (New) A pharmaceutical composition according to claim 50, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH₂, where a disulfide bond exists between the free thiols of the two Cys residues, or

H-D-Phe-Phe-Phe-D-Trp-Lys-Thr-Phe-Thr-NH₂.

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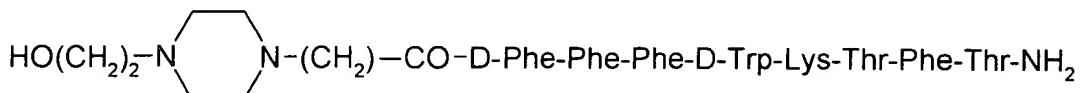
55. (New) A pharmaceutical composition according to claim 50, wherein said somatostatin type-5 receptor agonist is:

H-Cys-Phe-Phe-D-Trp-Lys-Ser-Phe-Cys-NH₂;

H-Cys-Phe-Tyr-D-Trp-Lys-Thr-Phe-Cys-NH₂;

H-Cys-Phe-Tyr(I)-D-Trp-Lys-Thr-Phe-Cys-NH₂;

wherein a disulfide bond exists between the free thiols of the two Cys residues in each of the foregoing agonists;



or

